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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,237	03/29/2006	John J. Kopchick	KOPCHICK=5A	8623

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
04/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,237	KOPCHICK ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 16-17, and 23-25, drawn to methods comprising administering an polypeptide which is substantially structurally identical or conservatively identical to a reference protein to a human subject, classified in class 514, subclass 2.

II. Claims 1, 16-17, and 22-25, drawn to methods comprising administering an expression vector encoding a polypeptide to a human subject, classified in class 514, subclass 44.

III. Claim 2, drawn to a method comprising administering an antagonist of a polypeptide to a human subject, classified in class 514, subclass 2.

IV. Claim 2, drawn to a method comprising administering an anti-sense vector to a human subject, classified in class 514, subclass 44.

V. Claim 3, drawn to a method comprising administering an "agent" which down-regulates expression of an "unfavorable" protein to a human subject, classified in class 514, subclass 1.

VI. Claim 3, drawn to a method comprising administering an "agent" which is an antagonist for the expression product of an "unfavorable" gene to a human subject, classified in class 514, subclass 1.

VII. Claim 3, drawn to a method comprising administering an "agent" which degrades an "unfavorable" protein to a human subject, classified in class 514, subclass 1.

VIII. Claim 3, drawn to a method comprising administering an "agent" which up-regulates expression of a "favorable" protein to a human subject, classified in class 514, subclass 1.

IX. Claim 3, drawn to a method comprising administering an "agent" which is an agonist of a "favorable" protein to a human subject, classified in class 514, subclass 1.

X. Claim 3, drawn to a method comprising administering an "agent" which inhibits the degradation of a "favorable" protein to a human subject, classified in class 514, subclass 1.

XI. Claim 3, drawn to a method comprising administering an "agent" which is the "favorable" protein to a human subject, classified in class 514, subclass 2.

XII. Claim 3, drawn to a method comprising administering an "agent" which is an expression vector encoding the "favorable" protein to a human subject, classified in class 514, subclass 44.

XIII. Claims 4, 7-15, 18-21, and 26-27, drawn to methods comprising assaying tissue or body fluid samples from a subject to determine the level of expression of a "favorable" gene, classified in class 435, subclass 4.

XIV. Claim 5, drawn to methods comprising assaying tissue or body fluid samples from a subject to determine the level of expression of an "unfavorable" gene, classified in class 435, subclass 4.

Claim 6 link(s) inventions XIII and XIV. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 6. Upon the indication

of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

1) Inventions I and II are directed to related methods. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed involve the administration of materially different molecules, as polypeptides and nucleic acid expression vector are materially different in physical, chemical, and functional properties, and have different modes or

operation and effects. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

2) Inventions III and IV are directed to related methods. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed involve the administration of materially different molecules, as antagonists of polypeptides and antisense nucleic acid expression vectors are materially different in physical, chemical, and functional properties, and have different modes of operation and effects. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

3) Inventions I and II and inventions III and IV are directed to related methods. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, methods of inventions I and II involve the administration of proteins or nucleic acids encoding proteins which are substantially or conservatively identical to a specific set of reference proteins, whereas the methods of inventions I and II involve the administration of antagonists or antisense nucleic acids which act on proteins substantially or conservatively identical to a completely different set of reference proteins. As such, the inventions as claimed involve the administration of materially

different molecules with materially different physical, chemical, and functional properties, and which have different modes of operation and effects. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

4) Inventions V-XII are directed to related methods. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, each invention utilizes an "agent" which has materially different properties, modes or operation, and functions. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

5) Inventions I-IV and inventions V-XII are directed to related methods. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, each of inventions I-IV involves the use of a polypeptide, nucleic acid encoding a polypeptide, antagonist of a polypeptide or antisense nucleic acid which is substantially or conservatively identical to a specific group of reference proteins. In contrast, the inventions of V-XII are drawn to the use of a variety of unrelated "agents" which act or either "favorable" or "unfavorable" genes or gene products. As such, the materials used in each method are materially different in design, modes or operation

and function. Furthermore, the inventions as claimed do not appear to encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

6) Inventions I-XII and inventions XIII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the methods of inventions I-XII require the administration of various molecules to a human subject, whereas the methods of inventions XIII-XIV are *in vitro* assays involving testing tissue for nucleic acids or proteins. As such, the methods are not capable of use together and have different designs and modes of operation.

7) Inventions XIII and XIV are directed to related methods. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are drawn to the detection of unrelated and materially different genes, "favorable" versus "unfavorable". As such, the inventions have different designs, modes or operation and functions. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I-IV and XIII-XIV require further restriction as follows, please note that this is NOT an election of species requirement, but a restriction requirement between independent and distinct inventions.

Each of inventions I-IV and XIII-XIV require the administration of or detection of proteins or nucleic acids substantially structurally or conservatively identical to a specific set of reference proteins or which are antagonists or antisense to proteins or nucleic acids substantially structurally or conservatively identical to a specific set of reference proteins. Each of the reference proteins as set forth in claim 1 or claim 2, for example, are unique proteins with unique amino acid sequences and further have materially different physical, chemical, structural, and functional properties. As such, methods of administering or detecting the various proteins, nucleic acids, antagonists or antisense nucleic acids related to each reference protein constitute materially different methods in design, mode or operation and function. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions V-XII require further restriction as follows, please note that this is NOT an election of species requirement, but a restriction requirement between independent and distinct inventions.

Each of inventions V-XII require the administration of various materially different "agents" which are either substantially identical to or act on "favorable" or "unfavorable" genes. The specification identifies numerous "favorable" or "unfavorable" genes, each of which is a unique nucleic acid sequence encoding a unique protein with unique amino acid sequence and which further each have materially different physical, chemical, structural, and functional properties. As such, methods of administering the various agents related to each "favorable" or "unfavorable" gene constitute materially different methods in design, mode or operation and

function. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically

point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note

that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/
Primary Examiner, A.U. 1633